12

**PATENT** 

'49 (Amended).

The polypeptide of claim 46 consisting of a monomer of  $\Omega$ .

63 C

The polypeptide of claim 49 wherein  $\Omega$  is

(ARQKQKHPKKVKQAFNPLI) (SEQ ID NO:6).

CA

52. (Amended)

The polypeptide of claim 4, in which the peptide units are mixtures of

two to four kinds of peptide units selected from the group consisting of  $\Phi$ ,  $\Gamma$ ,  $\Delta$  and  $\Omega$ .

#### REMARKS

Applicants would like to thank the Examiner for the telephonic interview conducted today in which it was agreed that in view of the amendments discussed (and presented above), the claims are in condition for allowance.

After entry of the above amendment, claims 34, 37-41, 43-52 will be pending. Claims 37, 38, 41, 44-50 and 52 have been amended to include SEQ ID NOs and to make the claims consistent with the formula in the independent claim. Claims 31 and 42 have been cancelled, without prejudice to their presentation in a continuing application. Attached hereto is a marked-up version of the changes made to the specification and claims by the present amendment. The attached page is captioned "Version with markings to show changes made".

- 4 -

61-

**PATENT** 

## **Formal Drawings**

Applicants acknowledge receipt of the "Attachment for PTO-948" outlining changes for prosecution of applications containing drawings. Formal drawings have been filed with the Draftsperson on June 10, 2002.

### **Supplemental Information Disclosure Statement**

Applicants submit herewith another copy of the Supplemental Information Disclosure Statement November 28, 2001 (received by the PTO on December 18, 2001). Applicants respectfully request that the Examiner initial and return the same with the next communication.

## **Objections**

Claims 31, 34, 37-44, 51 and 52 have been objected to for failing to include the SEQ ID NO. The claims have been amended to include this information. Applicants respectfully request reconsideration and withdrawal of the objection.

#### Rejections under 35 U.S.C. § 112, First Paragraph

Claims 31 and 42 stand rejected under 35 U.S.C. § 112, first paragraph, asallegedly lacking enablement. Applicants do not concur. However, solely for purposes of advancing prosecution, the claims have been cancelled, without prejudice to their presentation in a continuing application.

DOCKET NO.: ORGU-0023 PATENT

Claims 31, 34, 37-44 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support, and therefore, as allegedly constituting new matter. Applicants traverse the rejection.

The Office Action suggests that there is no support for the polypeptide of claim 41 or 52. Applicants direct the Examiner's attention to claim 1 as originally filed in parent serial no. PCT/US93/08699, filed September 15, 1993, which recites:

A polypeptide consisting essentially of an amino acid sequence selected from the group consisting of:

[X ETFTETWNRFITHTE Y]<sub>n</sub>, [X GMLEASEGLDGWIHG Y]<sub>n</sub>, [X HQQGGWSTLIEDNIP Y]<sub>n</sub>, and [X KQKHPKKVKQAFNPL Y]<sub>n</sub>,

wherein X and Y are independently from 0 to about 5 naturally occurring amino acids, wherein n is 1 to about 1000, wherein the polypeptide is capable of binding antibody in a specimen from an individual with Epstein-Barr virus (EBV)-associated disease.

In claim 41, as amended, X and Y have been replaced by  $\alpha$  and  $\beta$ , respectively.  $\phi$  represents the first peptide unit recited,  $\Gamma$  represents the second,  $\Delta$  the third and  $\Omega$  the fourth. As defined in originally filed claim 1, X and Y (and, therefore  $\alpha$  and  $\beta$  in the present claim) can be from 0 to about 5 naturally occurring amino acids. As such, if both  $\alpha$  and  $\beta$  are 5 amino acids, the total number of amino acids in the peptide unit is 25. If either  $\alpha$  or  $\beta$  is less than 5, then the total number of amino acids in the peptide unit is less than 25. Each peptide unit in original claim 1 includes a subscript n, defined as being 1 to about 1000, and which denotes the number of repeating units of that particular peptide unit. The subscript n has been deleted and the language incorporated into claim 41 as "[a] polypeptide consisting of a series of one to 1000 peptide units . . . . "

DOCKET NO.: ORGU-0023 PATENT

Furthermore, as reiterated in the previous response of record, the disclosure of the equation of claim 41 is found in the description of the invention, for example, on pages 8 and 9 of the specification.

The polypeptides of the invention can also be utilized as repeating units ranging from 1 to about 1000 units in length. These units can be homogeneous, for example, where all of the units are repeats of the same polypeptide or can be mixtures of the polypeptides of the invention.

(Specification page 8, line 28 - page 9, line 4). The symbols  $\Phi$ ,  $\Gamma$ ,  $\Delta$  and  $\Omega$  refer to the polypeptides of the invention used as peptide units, as defined on page 8, lines 25, and lines 20-24. The polypeptide of claim 41 can be homogenous for one kind of the peptide unit, or a mixture of the several kinds of peptide units.  $\Phi$ ,  $\Gamma$ ,  $\Delta$  and  $\Omega$  will be at least 15 amino acids in length because they contain the recited formula (explained above, and discussion incorporated by reference herein). As there is no recitation of a particular repeated multimer in the claims, there is no requirement for the disclosure of a specific multimer in the specification. Accordingly, Applicants assert that claim 41 does not contain new matter.

Claim 52 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support. As discussed above, the specification as originally filed, for example, on page 9, lines 2-4, recites "[t]hese units can be homogeneous, for example, where all of the units are repeats of the same polypeptide or can be mixtures of the polypeptides of the invention," or lines 12-13, which recite "[f]or example, the invention includes a polypeptide comprising SEQ ID NO:1 and SEQ ID NO:2, NO:3, or NO:4, or any combination of these . . . ." (emphasis added). As such, there is clear support for a polypeptide that comprises randomly ordered (or mixed) peptide units. However, solely for purposes of advancing prosecution, Applicants have amended the claim to more clearly recite the invention. As such, the claim as amended recites "the polypeptide of claim 41, in which

DOCKET NO.: ORGU-0023 PATENT

the peptide units are mixtures of two to four kinds of peptide units selected from the group consisting of  $\Phi$ ,  $\Gamma$ ,  $\Delta$  and  $\Omega$ ."

Claim 44 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for reciting "wherein o is 0 and p is 0," without antecedent basis in claim 41.

Applicants have amended the claims to address this rejection. In view of the foregoing,

Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph be withdrawn.

## Rejections under 35 U.S.C. §102

Claims 41-44 and 51 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Smith et al. WO 94/06470. Claims 41 and 44 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Pothen et al. Applicants reiterate that in view of the arguments above that the claims do not constitute new matter, Applicants are entitled to the claim of priority and therefore, the references no longer constitute prior art.

Claims 31, 34, 37-40 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Pearson et al. The claim recites the term "polypeptide consisting of an amino acid sequence having the formula . . ." Applicants respectfully submit that the Examiner has incorrectly interpreted the meaning of "consisting of" as open language. As explained in MPEP § 2113.03, "the transitional phrase 'consisting of' excludes any element, step, or ingredient not specified in the claim." Accordingly, the claims do not read on the disclosure in Pearson et al. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of all rejections.

Applicants submit that the present claims meet all the requirements for patentability and thank the Examiner again for the indication that upon entry of the above amendments, the application is in condition for allowance. Should there be any remaining issues, the undersigned respectfully requests the Examiner contact her to discuss these issues in order advance this application to allowance.

Respectfully submitted,

Emma R. Dailey

Registration No. 48,491

**PATENT** 

Date: August 5, 2002

WOODCOCK WASHBURN LLP One Liberty Place - 46th Floor, Philadelphia, PA 19103

Phone: (215) 568-3100 Fax: (215) 568-3439

**PATENT** 

# **VERSION WITH MARKINGS TO SHOW CHANGES MADE**

#### In the Claims

Please cancel claims 31 and 42, without prejudice. Please amend claims 37, 38, 41, and 44-50 as follows:

37 (Amended). A polypeptide consisting of an amino acid sequence having the formula:

 $(\phi)_n$ 

wherein n is 1 to about 1000 and  $\phi$  is 25 amino acids or less and has the formula:

( $\alpha$  ETFTETWNRFITHTE  $\beta$ )<sub>n</sub> (SEQ. ID NO:1)

wherein  $\alpha$  and  $\beta$  are independently from 0 to about 5 naturally occurring amino acids, wherein the polypeptide is capable of binding antibody in a specimen from an individual with Epst in Barr virus (EBV)-associated disease.

38 (**Amended**). The polypeptide of claim 37 wherein φ is QNSETFTETWNRFITHTEHVD (SEQ ID NO:5).

41. (Amended) A polypeptide consisting of a series of one to 1000 peptide units selected from the group consisting of peptide units  $\Phi$ ,  $\Gamma$ ,  $\Delta$  and  $\Omega$ , wherein:

 $\Phi$  is 25 amino acids or less and has the formula ( $\alpha$ ETFTETWNRFITHTE $\beta$ ) (SEQ ID NO:1),

 $\Gamma$  is 25 amino acids or less and has the formula ( $\alpha$ GMLEASEGLDGWIHQ $\beta$ ) (SEQ ID NO:2),

**PATENT** 

 $\Delta$  is 25 amino acids or less and has the formula ( $\alpha$ HQQGGWSTLIEDNIP $\beta$ ) (SEQ ID NO:3),

 $\Omega$  is 25 amino acids or less and has the formula ( $\alpha$ KQKHPKKVKQAFNPL $\beta$ ) (SEQ ID NO:4),

 $\alpha$  and  $\beta$  are each independently from 0 to 5 naturally occurring amino acids, and the polypeptide is capable of binding antibody in a specimen from an individual with Epstein-Barr virus (EBV)-associated disease.

44 (Amended). The polypeptide of claim 41 [wherein o is 0 and p is 0] consisting of the peptide units  $\phi$  and  $\Omega$ .

45 (Amended). The polypeptide of claim 44 wherein  $\phi$  is (QNSETFTETWNRFITHTEHVD) (SEQ ID NO:5) and  $\Omega$  is (ARQKQKHPKKVKQAFNPLI) (SEQ ID NO:6).

46 (Amended). The polypeptide of claim 41 wherein  $\phi$  is (QNSETFTETWNRFITHTEHVD) (SEQ ID NO:5) and  $\Omega$  is (ARQKQKHPKKVKQAFNPLI) (SEQ ID NO:6).

47(Amended). The polypeptide of claim 41 wherein  $\Omega$  is (ARQKQKHPKKVKQAFNPLI) (SEQ ID NO:6).

**PATENT** 

48(Amended). The polypeptide of claim 41 [wherein n is 0, o is 0 and p is 0] consisting of repeating units of  $\Omega$ .

49 (Amended). The polypeptide of claim 48 [wherein q is 1] consisting of a monomer of  $\Omega$ .

50 (Amended). The polypeptide of claim 49 wherein  $\Omega$  is (ARQKQKHPKKVKQAFNPLI) (SEQ ID NO:6).

52. (Amended) The polypeptide of claim 41, in which the peptide units are [randomly ordered in a series consisting] <u>mixtures</u> of two to four kinds of peptide units selected from the group consisting of  $\Phi$ ,  $\Gamma$ ,  $\Delta$  and  $\Omega$ .